

ELUTION OF POLYVINYLPIRROLIDONE AND THE STORAGE PERIOD OF A γ -STERILIZED POLYSULFONE MEMBRANE DIALYZER

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OBJECTIVES

Polyvinylpyrrolidone (PVP) plays an important role as a hydrophilic agent in polysulfone (PS) dialysis membranes, but it also causes problems such as anaphylaxis and skin lesions when it is eluted from the membrane surface. It has been reported that the extent of PVP elution depends on the type of dialyzer (wet- or dry-type), the method of sterilizing the dialyzer (autoclave or γ -radiation), and the storage period of the dialyzer.

The objective of this study was to investigate the relationship between elution of PVP and the storage period of a γ -sterilized wet-type PS membrane dialyzer.

METHODS

Ten APS-15SA dialyzers (APS, Asahi Kasei Medical Co., Ltd.) sterilized by γ -radiation with a storage period of 67 to 1041 days were washed with 1.0 L of physiological saline and the concentration of PVP eluted from the PS membrane was measured in the washings. In addition, experimental use of each dialyzer was performed by circulating physiological saline for 4 hours, after which PVP eluted from the membrane was measured.

Then these two amounts were summed to obtain the total amount of PVP eluted from the membrane after which the correlation between elution of PVP and the storage period was analyzed.

RESULTS

The amount of PVP eluted into the washings from the dialyzer membrane was significantly correlated with the storage period ($r=0.977$, $p<0.01$) (Fig.1).

However, the amount of PVP eluted from dialyzers with a medium storage periods of 164 to 275 days in the circulation experiment was 2.7 ± 0.6 mg (mean \pm S.D. $n=5$), which was significantly more than the amount of PVP eluted from dialyzers with a long storage period of 549 to 1091 days (1.3 ± 0.1 mg, $n=3$) ($P<0.05$). It was also significantly more than the amount of PVP eluted from dialyzers with a short storage period of 67 or 80 days (0.1 and 0.4 mg, respectively), which were very low levels (Fig.2).

The total amount of PVP eluted from the dialyzer membranes in both the washings and during circulation was significantly correlated with the storage period ($r=0.986$).

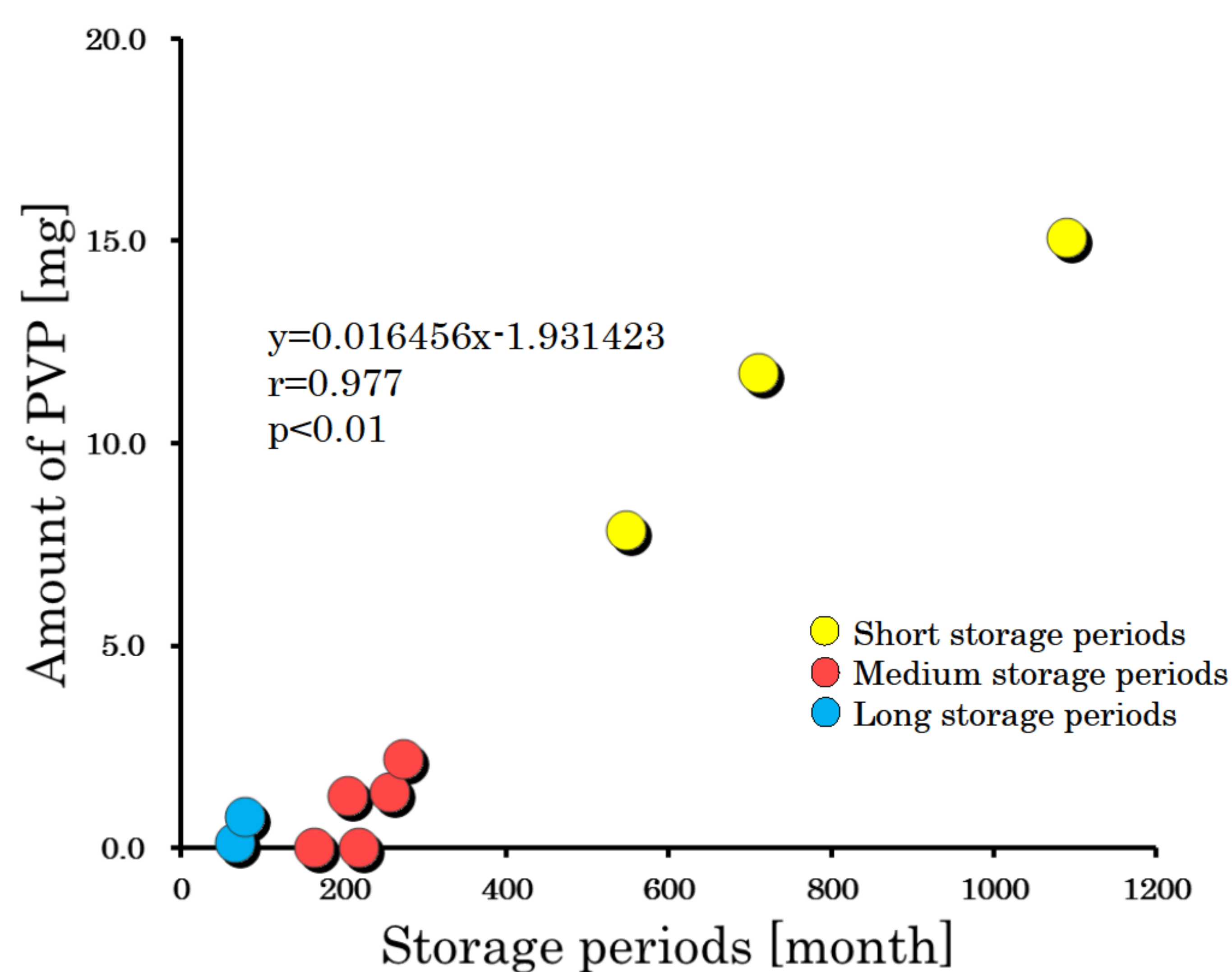


Fig.1 Relation between amount of PVP eluted into the washings and storage periods

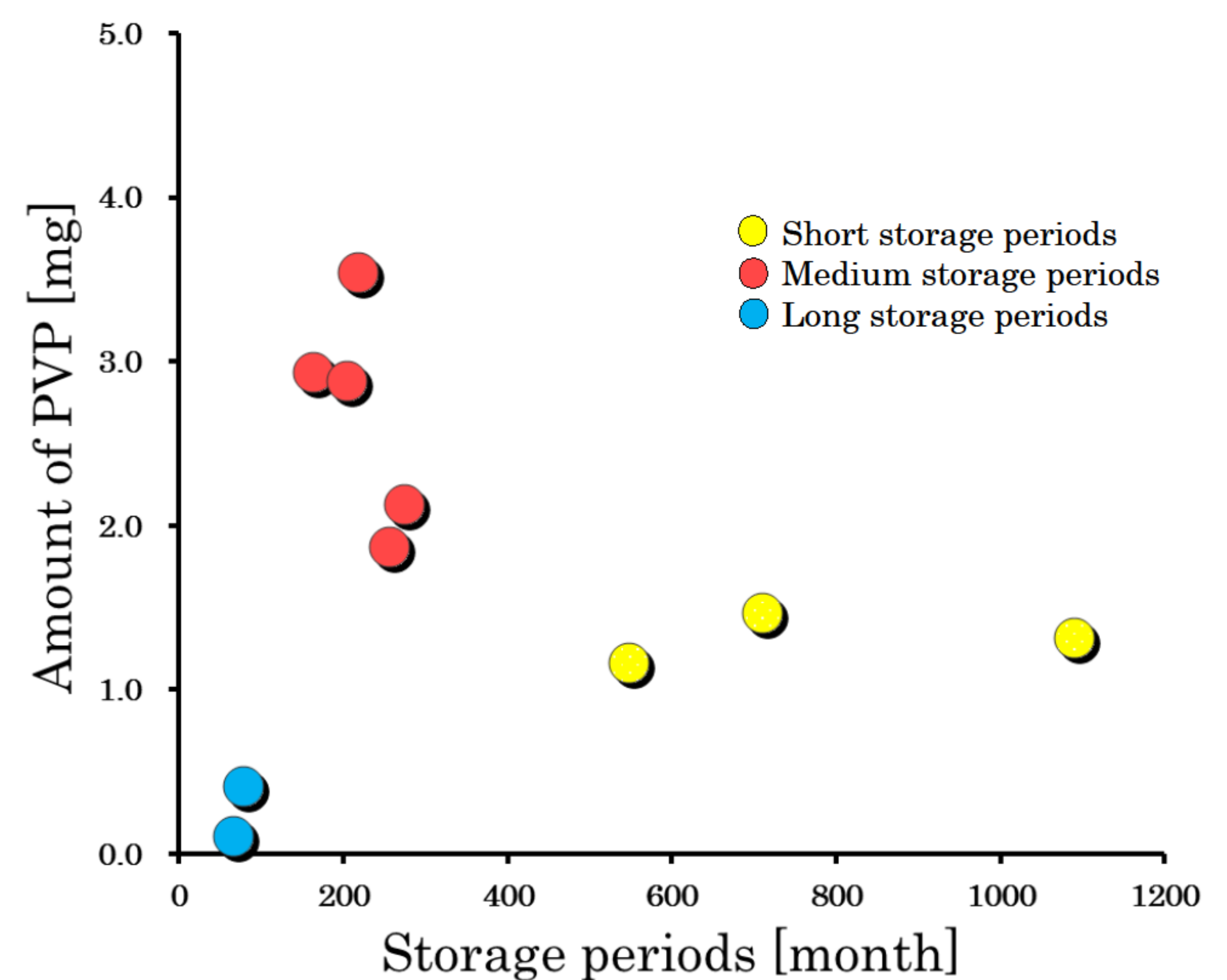


Fig.2 Comparison of eluted PVP levels in the circulation experiment among different storage periods

CONCLUSIONS

The amount of PVP eluted by washing γ -sterilized wet-type PS dialyzers increased along with the storage period. However, the circulation experiment showed that more PVP was eluted from dialyzers with a medium storage period than from dialyzers with a short or long storage period. Since dialyzers with a medium storage period are most often used in the clinical setting, it should be noted that the amount of PVP delivered to the patient is increased by employing medium storage period γ -sterilized wet-type PS membrane dialyzers.

REFERENCES:

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